

REGISTRATION

35935-83

# ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: 7/19/10		EPA Reg. Number: 35935-16		
	Check List Item	Yes	No	N/A
1	Has the <b>PRIA Fee been Paid</b> ; is a copy of the check or Pay.gov receipt included in the Submission Package?	✓		
2	Is an <b>Application Form</b> (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	✓		
3	Is a <b>Confidential Statement of Formula</b> (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	✓		
4	Is a <b>Formulator's Exemption Statement</b> (EPA Form 8570-27) Included in the Submission Package?	✓		
5	Is a <b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) Included in the Submission Package?		✓	
6	Is a <b>Data Matrix</b> (EPA Form 8570-35) Included in the Submission Package?		✓	
7	Is a <b>Label</b> Included in the Submission Package?	✓		
8	Are <b>Data</b> Included in the Submission Package?		✓	
9	Is the Submission an Amendment?		✓	

## NEW APPLICATIONS

DATE: 1/21/10

FILE NUMBER: 35935-14

FEP (OPPIN ENTRY) per 1/21/10  
(Initial & date)

FILE ROOM: pm 1/29/10  
(Initial & date)

SIG: \_\_\_\_\_  
(Initial & date)

FILE ROOM: \_\_\_\_\_  
(Initial & date)

X ASSIGN TO PM 25 (NO DATA)

     JACKET TO SHELF (DATA)

*due Nov. 10, 2010*

# Material to be added to an e-Jacket

Reg. No. 35935-83

## 1.Placement within the e-Jacket:

✓ Default: chronological top

Other: (PDF page number, i.e., "before page 45")

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## 2.Is this material:

✓ Newly stamped accepted label

Notification

✓ New CSF

Final Printed Label

Other: \_\_\_\_\_

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3.Attach this notice on top of the material. It must be clipped all together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Phil Errico

Phone: 305-6663 Division: RD

Date: 11/17/2010



Response to registration request for Nufarm Picloram Technical, EPA Reg.  
No. 35935-83 with attachment.

Philip Errico to: George Meindl

11/17/2010 12:47 PM

Cc: Jim Tompkins

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Mr. Meindl,

Please see the attached response to registration request for Nufarm Picloram Technical, EPA Reg. No. 35935-83.

Best Regards,



EPA REG NO 35935-83, NOV 9, 2010, NUFARM PICLORAM TECH.pdf

Philip (Phil) V. Errico , Senior Chemist  
U. S. Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division/Herbicide Branch (7505C)  
Phone: 703-305-6663  
Fax: 703-308-1825  
Email: Errico.Philip@epa.gov



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

35935-83

Date of Issuance:

NOV 09 2010

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

NUFARM PICLORAM  
TECHNICAL

Name and Address of Registrant (include ZIP Code):

Nufarm Limited  
150 Harvester Dr. Suite 200  
Burr Ridge, IL 60527

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for registration review of your product under FIFRA section 3(g).

The requested draft label as submitted is not acceptable. It will be acceptable if the following changes to the label are made before shipping any product:

- Change the product registration number to "EPA Reg. No. 35935-83".
- Add the establishment number.
- Add the batch number to all products in disposable containers before shipment.
- On page 2, under "DIRECTIONS FOR USE", change the fourth sentence starting with "Uses for which the USEPA has accepted, etc." to "This product may be used to formulate products for specific use(s) not listed on the manufacturing use product label if: 1. The formulator, user group or grower has complied with U.S. EPA submission requirements to support such use(s), and 2. End-use products have EPA an approved stewardship program in place.
- On page 3, under "WARRANTY DISCLAIMER", add to the second sentence "TO THE EXTENT CONSISTENT WITH APPLICABLE LAW" before "...ASSUMED BY BUYER OR USER."

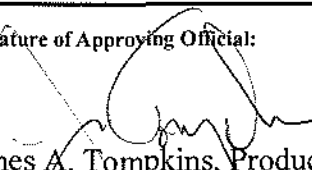
A stamped accepted label with comments is enclosed for your files.

Submit one copy of the revised final printed label for the record before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Please contact Phil Errico at 703-305-6663/ [errico.philip@epa.com](mailto:errico.philip@epa.com) .

Signature of Approving Official:



James A. Tompkins, Product Manager (25)  
Herbicide Branch, Registration Division (7505P)

Date:

NOV 09 2010

EPA Form 8570-6

Enclosure: Label stamped "Accepted With Comments".

# NUFARM PICLORAM TECHNICAL

FOR MANUFACTURING USE ONLY

## ACTIVE INGREDIENT:

Picloram: 4-amino-3, 5, 6-trichloropyridine-2-carboxylic acid . . . . . 93%

OTHER INGREDIENTS: . . . . . 7%

TOTAL: . . . . . 100%

KEEP OUT OF REACH OF CHILDREN

## WARNING

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

For Chemical Spill, Leak, Fire or Exposure, Call CHEMTREC 800-424-9300  
For Medical Emergencies Only, Call 877-325-1840

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

## WARNING - AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated**

NOV 09 2010

EPA Reg. No. 35935-xx

NET CONTENTS:

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.**

35935-83

Manufactured For:  
Nufarm Limited  
RTP, NC 27709

EPA Est. No.

## ENVIRONMENTAL HAZARDS

This pesticide is toxic to some plants at very low concentrations. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the ERA.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

Rangeland and permanent grass pastures, barley, oats and wheat, fallow cropland, Conservation Reserve Program (CRP), forests and non-cropland. Because of their properties and intended uses, herbicidal formulations containing this product will require precautionary labeling differing from that given. Formulators should develop their own use and precautionary labeling, based on the properties and intended uses of their finished formulations and are responsible for obtaining EPA registration for these products.

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.

For experimental use purposes that are in compliance with USEPA requirements.

Consult Nufarm, Inc. for formulation and other information.

## HANDLING PRECAUTIONS

Do not contaminate water. Do not allow this product to contaminate water used for irrigation, drinking or other domestic purposes. Do not clean containers near water used for these purposes.

Do not contaminate atmosphere. When formulating dry products, do not allow dust particles from this product to contaminate the atmosphere. Small amounts may injure certain broadleaf plants.

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in a cool, dry, well-ventilated area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest ERA regional office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty inner liner by shaking and tapping sides and bottom to loosen clinging particles. Then empty residue into formulation equipment. Dispose of inner liner in a secure landfill or by incineration if allowed by state and local authorities. Offer for recycling, if available. Offer for reconditioning, if appropriate. If drum cannot be recycled or reconditioned, puncture and dispose of in a secure sanitary landfill, or by other

procedures approved by state and local authorities.

#### WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

#### LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BY WAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR ARISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(NEW)

*working copy*

# NUFARM PICLORAM TECHNICAL

FOR MANUFACTURING USE ONLY

*see p. 2  
then O.K.*

## ACTIVE INGREDIENT:

Picloram: 4-amino-3, 5, 6-trichloropyridine-2-carboxylic acid ..... 93%

OTHER INGREDIENTS: ..... 7%

TOTAL: ..... 100%

KEEP OUT OF REACH OF CHILDREN

## WARNING

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

For Chemical Spill, Leak, Fire or Exposure, Call CHEMTREC 800-424-9300  
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### WARNING - AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

EPA Reg. No. 35935-xx

EPA Est. No.

NET CONTENTS:

Manufactured For:  
Nufarm Limited  
RTP, NC 27709

## ENVIRONMENTAL HAZARDS

This pesticide is toxic to some plants at very low concentrations. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the ERA.

## DIRECTIONS FOR USE

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This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

Rangeland and permanent grass pastures, barley, oats and wheat, fallow cropland, Conservation Reserve Program (CRP), forests and non-cropland. Because of their properties and intended uses, herbicidal formulations containing this product will require precautionary labeling differing from that given. Formulators should develop their own use and precautionary labeling, based on the properties and intended uses of their finished formulations and are responsible for obtaining EPA registration for these products.

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.

*End-use products which have an EPA approved stewardship program in place.*

For experimental use purposes that are in compliance with USEPA requirements.

Consult Nufarm, Inc. for formulation and other information.

*all sentence*

## HANDLING PRECAUTIONS

Do not contaminate water. Do not allow this product to contaminate water used for irrigation, drinking or other domestic purposes. Do not clean containers near water used for these purposes.

Do not contaminate atmosphere. When formulating dry products, do not allow dust particles from this product to contaminate the atmosphere. Small amounts may injure certain broadleaf plants.

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in a cool, dry, well-ventilated area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest ERA regional office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty inner liner by shaking and tapping sides and bottom to loosen clinging particles. Then empty residue into formulation equipment. Dispose of inner liner in a secure landfill or by incineration if allowed by state and local authorities. Offer for recycling, if available. Offer for reconditioning, if appropriate. If drum cannot be recycled or reconditioned, puncture and dispose of in a secure sanitary landfill, or by other

procedures approved by state and local authorities.

#### WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

#### LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BY WAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR ARISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(NEW)

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 7-19-10 <sup>3/23/09</sup>  
 Experts In-Processing Signature: B. R Date 7-23-10 Fee Paid: Yes ☒  
 Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>35935-IG</u>		EPA Receipt Date: <u>7-19-10</u>							
Items for Review			Yes	No	N/A*				
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type		X						
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)		X						
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="text-align: center; padding: 2px;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no								
X									
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)				X				
	Certificate and data matrix consistent								
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
	If applicable, is there a letter of Authorization for exclusive use only.								
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)		X						
5	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)				X				
	a) Selective Method (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
	b) Cite-All (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
	c) Applicant owns all data (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )		X						

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)			X
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			X
	a) List study (or studies) not included with application			

**Comments:**

NO DATA ASSOCIATED WITH THIS SUBMISSION.

100% REPACK.

\* N/A – Not Applicable

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### **Unapproved Inerts Identified on CSFs**

##### **All applications except conventional new products and PIPs**

Once an **unapproved inert** is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PR1A category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

# R 300 and 301

100% identical (repack): YES or NO (circle one)

{If yes, it's a 100% repack - then Group A and B product chemistry data are not required}

Data on Group and A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition		<input checked="" type="checkbox"/>
830.1600	Description of materials used to produce the product		<input type="checkbox"/>
830.1650	Description of formulation process		<input type="checkbox"/>
830.1670	Discussion on the formation of impurities		<input type="checkbox"/>
830.1700	Preliminary analysis		<input type="checkbox"/>
830.1750	Certified limits (158.345)		<input type="checkbox"/>
830.1800	Enforcement analytical method		<input type="checkbox"/>

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color		<input checked="" type="checkbox"/>
830.6303	Physical State		<input type="checkbox"/>
830.6304	Odor		<input type="checkbox"/>
830.6314	Oxidation/Reduction (Chemical incompatibility)		<input type="checkbox"/>
830.6315	Flammability		<input type="checkbox"/>
830.6316	Explodability		<input type="checkbox"/>
830.6317	Storage stability		<input type="checkbox"/>
830.6319	Miscibility		<input type="checkbox"/>
830.6320	Corrosion Characteristics		<input type="checkbox"/>
830.6321	Dielectric Breakdown voltage		<input type="checkbox"/>
830.7000	pH		<input type="checkbox"/>
830.7100	Viscosity		<input type="checkbox"/>
830.7300	Density		<input type="checkbox"/>

## R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
830.1100	Acute Oral (LD50)		<input checked="" type="checkbox"/>
830.1200	Acute Dermal (LD50)		↓
830.1300	Acute Inhalation (LC50)		
830.2400	Acute Eye Irritation		
830.2500	Acute Dermal Irritation		
830.2600	Dermal Sensitization		

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited	
		Yes	No
810.3100	Soil Treatments for Imported Fire Ants		<input checked="" type="checkbox"/>
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments		↓
810.3300	Treatments to Control Pests of Humans and Pets		
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments		
810.3500	Premises Treatments		
810.3600	Structural Treatments		
810.3800	Methods for Efficacy Testing of Termite Baits		↓



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

July 22, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-437501  
EPA File Symbol or Registration Number: 35935-IG  
Product Name: NUFARM PICLORAM TECHNICAL  
EPA Receipt Date: 19-Jul-2010  
EPA Company Number: 35935  
Company Name: NUFARM LIMITED

WILLIAM M. MAHLBURG  
NUFARM LIMITED  
NUFARM LIMITED  
PO Box 13439  
RTP, NC 27709-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely, *Peresa Downs*  
Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{878862L~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☐ Studies?      ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.    25

Receipt No.

S-

878862

EPA File Symbol/Reg. No.

35935-IG

Pin-Punch Date:

7/19/2010

- ☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

R300

Granted:

R300

Amount Due: \$ 1365.00

100% repack

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer:

*[Signature]*

Date:

7/22/10

Remarks:

# Receipt for Section 3

S: 878862

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 35935 NUFARM LIMITED V

Risk Manager: Registration Division Risk Management Team 25

Product #: 35935-IG Product Name: NUFARM PICLORAM TECHNICAL

Override:

Me Too  
Section3:

Application Date: 19-Jul-2010

OPP Rec'd Date: 19-Jul-2010

Front End Date: 21-Jul-2010

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

CSF

Paper Label

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

\*Product ingredient source information may be entitled to confidential treatment\*

## Online Payment

## Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

## Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 2515JCUQ

Agency Tracking ID: 74127619035

Transaction Date and Time: 07/20/2010 12:10 EDT

## Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: George Meindl 150 Harvester Billing Address: Drive Billing Address 2: Suite 200 City: Burr Ridge State / Province: IL Zip / Postal Code: 60527 Country: USA	Card Type: Master Card Card Number: *****1276 Decision Number: Registration Number: Company Name: Nufarm Limited Company Number: 35935 Action Code: R300	Payment Amount: \$1,365.00 Transaction Date 07/20/2010 and Time: 12:10 EDT



Nufarm Limited  
George Meindl  
Regulatory Affairs Manager  
150 Harvester Drive, Suite 200  
Burr Ridge, IL 60527  
Phone: 630.455.2017 Fax: 630.455.2030  
[george.meindl@us.nufarm.com](mailto:george.meindl@us.nufarm.com)

July 20, 2010

Via Overnight Courier

James Tompkins (PM-25)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U. S. Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Subject: Nufarm Picloram Technical  
EPA Reg. No. 35935-  
Application for Repack Registration  
Fast track request - R300 44

Dear Mr. Tompkins:

Nufarm Limited is interested in registering the subject product. Under the Pesticide Registration Improvement Act of 2007 it is our opinion that this action falls under category R300 44, new product fast track. We believe this is the appropriate category since this application is for a repack of an existing registration. Therefore, Nufarm anticipates this action requires a fee of \$ 1,365 for this registration request and we would anticipate a three-month review time. We have prepaid the PRIA II fee, with copy of the pay.gov receipt included in this submission

To process this request please find attached the following documentation:

- Application for Pesticide – EPA form 8570-1
- Confidential Statement of Formula – EPA form 8570-4
- Formulators Exemption Statement – EPA form 8570-27
- Proposed labeling – four (4) copies

If you should have any questions regarding this matter, feel free to contact me at 630.455.2017 or email at [george.meindl@us.nufarm.com](mailto:george.meindl@us.nufarm.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'George Meindl', written over a faint, larger version of the same signature.

George Meindl  
Regulatory Affairs Manager  
Nufarm Limited



United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address  Nufarm Limited 150 Harvester Drive Suite 200 Burr Ridge, IL 60527	EPA File Symbol/Registration Number 35935-
	Product Name Nufarm Picloram Technical
	Date of Confidential Statement of Formula (EPA Form 8570-4) 07/19/2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Picloram

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
picloram		
Signature:	Name and Title George Meindl - Reg. Affairs Mgr.	Date: 07/19/2010

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

<b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number  
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 35935-19		2. EPA Product Manager James Tompkins	
4. Company/Product (Name) Nufarm Picloram Technical		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Nufarm Limited 150 Harvester Drive Suite 200 Burr Ridge, IL 60527 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. [REDACTED] Product Name [REDACTED]	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - Explain below. [REDACTED]	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) R300 44 New product registration request - fast track \$1365.00 3 month review Repack of [REDACTED]			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 kg container	
5. Location of Label Directions <input type="checkbox"/>		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name George Meindl (george.meindl@us.nufarm.com)		Title Regulatory Affairs Manager	
		Telephone No. (Include Area Code) 630.455.2017	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name George Meindl		5. Date 7/19/2010	

\*Product ingredient source information may be entitled to confidential treatment\*

\*Confidential Statement of Formula may be entitled to confidential treatment\*